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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/619,237
Filing Date: July 14, 2003
Appellant(s): SMEDEGAARD, JORGEN K.

Marc A. Began
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/09/08 appealing from the Office action mailed 1/11/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,848,991	GROSS	12-1998

For the above reasons, it is believed that the rejections should be sustained.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 30, 32-34 are rejected under 35 U.S.C. 103(a) as obvious over Gross et al (US 5848991). Gross discloses a method of treating a patient with a disease comprising the steps of providing a delivery device having a lower surface with adhesive means adapted to be attached to the skin surface of a patient (Col. 3, lines 46-47), delivering therapeutic agent to the patient during a period of sleep, removing the device after the period of sleep (Col. 4, lines 55-65). Gross does not explicitly disclose that the device delivers fluid for a period of 7-9 hours. However, Gross does disclose that the device delivers fluid during sleep which is obviously approximately 7-9 hours. Gross discloses that the reservoir can hold 0.2-10 mL of fluid which is capable of containing 5-50 IU of insulin. Gross further discloses that it may be desirable to deliver certain drugs only when required by the subject (Col. 5, lines 1-2).

3. The claim does not require that the patient only wear the device during sleep times. The claim only requires that during a period between two sleep times the patient wears no device. The claim does not require that no device be worn for the entire time between two sleep periods. Since Gross teaches separate nighttime and daytime devices, there is *a period* when the user removes the nighttime device in preparation for applying the daytime device wherein no device is attached to the patient.

(10) Response to Argument

4. Applicant's arguments submitted with the Appeal Brief filed 12/09/08 have been fully considered and are not persuasive.

5. Applicant argues that Gross does not teach an insulin therapy regime where the awake-time insulin requirement would go to zero. The examiner disagrees with this assertion, but first the examiner would like to clarify exactly what is required by the claim. Applicant's statement mischaracterizes the claim. The examiner will attempt to show that the claim requires only that the device deliver insulin over a 7-9 hour period, at which point the device is removed from the skin for a period of time. The claim requires that "fluid communication is established at a time after which the patient is expected to sleep…" This language provides very little limitation to the claim. "A time after which" does not provide any definite boundaries. Assuming the patient keeps what is generally accepted to be a normal sleep schedule, any point in time while the patient is awake is a time "after which" the patient is expected to sleep. In fact, even if the patient does not keep normal sleeping hours, all humans must sleep at some point, so any point in time at all is a time after which the patient is expected to sleep. Furthermore, the patient is only "expected to sleep". Who is expecting the patient to sleep? This is a very indefinite limitation, and the examiner is interpreting it to support the assumption that any point in time is a time after which the patient is expected to sleep.

6. Next, the claim states that "no delivery device is attached to a skin surface... during a period between two periods of sleep...". This only means that after the 7-9 hours the device is removed for SOME period of time. The claim does not state that no device is attached for the entire time between two periods of sleep. The claim requires that no device be attached for a

period between two periods. That period could be one second or the entire time between two periods of sleep. Furthermore, how could one be sure that the patient is not going to sleep for 7-9 hours then wake up for five minutes then go back to sleep for 7-9 hours? Therefore, this limitation does not lend support to applicant's characterization of the claim.

7. Now that the requirements of the claim have been made clear, the examiner will show that Gross clearly anticipates the claim. Gross discloses a device for delivery of insulin that is attached to the skin of the patient. Gross further discloses that the patient may be provided with two separate devices, a daytime and a nighttime device (col. 4, lines 64-67). The use of the nighttime device meets the requirements of delivery during a 7-9 hour period when the patient is expected to sleep. Upon waking, the patient removes the nighttime device. Now applicant asserts that there is no teaching in Gross to forgo the daytime device. The examiner does not necessarily agree with this statement, but believes it does not matter. When the nighttime device is removed in preparation for applying the daytime device, there is a period (between two sleep periods) wherein the patient is wearing no device. Therefore, this meets the claim limitation.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Laura A Bouchelle/

Examiner, Art Unit 3763

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